REMARKS

The Office action dated February 5, 2008 is acknowledged. Claims 1-19 and 21-33 are pending in the instant application. According to the Office action, claims 1-8, 17-19 and 21 are rejected and claims 9-16 and 22-23 have been withdrawn. By the present Office Action response, claims 1, 3, 4, 6, 18 and 21 have been amended and claims 34 and 35 have been added. Claims 34 and 35 respectively recite that "cannabis extract" is "cannabis oil" which is a type of cannabis extract, and further define the group of cannabinoids recited in claim 1. Support may be found throughout the present specification, such as at paragraphs [0009] and [00010]. Reconsideration is respectfully requested in light of the amendments being made hereby and the arguments made herein. No new matter has been added.

Priority

As requested by the Examiner by telephone conference on May 28, 2008, an English translation of the German priority application is enclosed herewith. It is believed that this submission will resolve the issue of priority discussed on page 4 of the Office action.

Objection to the Abstract

The Examiner has objected to the Abstract. The Abstract has been amended, as set forth above. Withdrawal of this objection is respectfully requested.

Rejection of Claims 1, 3, 6, 18 and 21 under 35 U.S.C. 112, second paragraph

Claims 1, 3, 6, 18 and 21 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. The Examiner states that the

terms "cannabis extract" and "cannabis oil" in claim 1 lack clarity, i.e., the terms are vague and indefinite because neither the claim nor the specification define the composition of the extract or the oil, or the means through which either is to be acquired.

Claim 1 has been amended accordingly. However, it is respectfully submitted that the term "cannabis extract" in the context of pharmaceutical preparations is generally understood in the art to refer to heterogenous mixtures of substances which are extracted (e.g., by organic solvents) from natural products such as plants or plant parts (i.e., seeds, flowers, etc.). As set forth in the present specification (such as in paragraph [00003]), the term "cannabis extract" relates to extracts prepared from the Indian hemp plant *Cannabis sativa* (hence the name "cannabis extract"). Claim 1 has thus been amended as set forth above to clarify that the presently claimed invention does not pertain to chemically pure tetrahydrocannabinol (THC), but rather to extracts comprising a mixture of different cannabinoid substances. In particular, claim 1 has been amended as set forth above to recite that the present invention pertains to extract which contain tetrahydrocannabinol (THC) in combination with other cannabinoids. In this regard, the Applicant encloses herewith a copy of pages from "Rompp Lexikon Chemie" which is a standard chemical encyclopedia. In the entry designated "Haschisch," the document explains that the official international name of hashish is "cannabis" and that "hashish oil," which is also referred to as "cannabis extract," contains THC together with a variety of other cannabinoids. It is submitted that this further supports the Applicant's position that the use of the term "cannabis extract" does not result in a lack of clarify in the present claims. It is noted that the Applicant can submit an English translation of these pages if the Exminer wishes.

The Examiner states that the term "and/or" in claim 3 is a relative term which renders the claim indefinite. Claim 3 has been amended accordingly.

The Examiner states that claim 6 recites the limitation "the layer thickness" in the first and second lines of the claim, but that there is insufficient antecedent basis for this limitation in the claim. Claim 6 has been amended accordingly.

Regarding the "layer" limitation in claims 6 and 21, the Examiner states that it is not clear to which layer of the administration form the Applicant is referring. These claims have been amended accordingly.

Rejection of Claims 1-3, 5-8, 17, 19 and 21 under 35 U.S.C. 102(b)

Claims 1-3, 5-8, 17, 19 and 21 have been rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,319,510 (Yates). The Examiner states that Yates teaches each and every limitation of claims 1-3, 5-8, 17, 19 and 21. In particular, the Examiner states that Yates teaches a multi-layered, "gum-pad" composition for use in the mouth of a person wherein a second adjacent layer contains the medication, is capable of being liquefied by saliva and is made to form a reservoir (i.e., contained between two layers) and that claim 16 teaches dronabinol as the active agent used in the gum pad. The Examiner further states that the reservoir layer is taught to contain the medication which is mixed or compounded with: (1) water soluble particulate material, or (2) water soluble support matrix (col. 7, line 66 – col. 8, line 1). The Examiner also states that Yates further provides a listing of different materials useable in either of the two aforementioned matrices, such as collagen, cellulose derivatives, etc. (col. 8, lines 2-54). Regarding the composition of the matrix, the Examiner argues that Yates teaches that a hydrogel matrix may be comprised of approximately 20% wt. to 85% wt. of hydrophilic

polymer (col. 10, lines 13-15), and flavoring agents, such as mint, and sweeteners. Still further, the Examiner states that Yates teaches different individual layers of the gum pad composition that have thicknesses within the recited ranges, the high flux, semi-permeable membrane materials can have a thickness of 1-10 mils (col. 13, lines 25-26), which converts to a range of 0.025 mm to 0.25 mm and that the thickness of the backing layer is in the range from 0.3 mm to 3.0 mm. Therefore, the Examiner concludes that Yates discloses the presently claimed invention.

The Applicant respectfully disagrees with the Examiner's assessment. It is respectfully submitted that Yates fails to disclose an administration form containing a cannabis extract in accordance with present claim 1. It is respectfully noted that the Office action states on page 3 (lines 4-6) that Dronabinol (also mentioned by Yates – col. 19, lines 55-61 & claim 16) is prepared by dissolving THC in sesame oil and that the Examiner refers to THC as being "the main extract from cannabis." The Applicant respectfully disagrees since the term "extract," in the field of pharmaceuticals, is generally used to refer to compositions containing mixtures of various substances in varying amounts rather than to an isolated substance which was prepared in a chemically pure form. As discussed above, the term "cannabis extract" relates to extracts prepared from the Indian hemp plant *Cannabis sativa* and the extract in accordance with the present invention contains tetrahydrocannabinol (THC) in combination with other cannabinoids. Therefore, THC cannot be regarded as a cannabis extract but rather THC is a cannabinoid substance which is present within a cannabis extract.

Moreover, when THC is dissolved in sesame oil (as in Dronabinol), this solution would not be referred to as "cannabis oil" by a person of ordinary skill in the art. The

term "cannabis oil" relates to an oily extract which is prepared from hemp plants and which contains a mixture of various cannabinoid substances together with other plant substances not belonging to cannabinoids.

In addition, it is submitted that present claim 1 further recites that the administration form has a thickness of 0.5 mm or less. This limitation is also not set forth in Yates. As noted by the Examiner in the Office action (page 8), Yates indicates the thickness of the backing layer and the membrane, but fails to specify the thickness of the reservoir which is the second layer of the three layers which form the "gum pad" (claim 1 of Yates). As can be inferred from Figure 6 of Yates, the reservoir layer (14) is considerably thicker than the other two layers (backing layer, membrane) which have a total thickness of at least 0.325 mm (as noted in the Office action, page 10, lines 1-2). As the backing layer (12) of Yates encloses the reservoir from all sides (claim 1; Figure 6), the resulting contribution of the backing layer to the total thickness of the pad is twice the minimum thickness (i.e., 2 X 0.3 mm = 0.6 mm; see Yates, col. 7, lines 5-7; Office action, page 8, lines 15-16). Hence, the combined thickness of the backing layer and the membrane amounts to at least 0.625 mm. The total thickness of the gum pad, further including the reservoir layer which is much thicker than the backing layer or reservoir, considerably exceeds the limitation of "thickness of 0.5 mm or less" as recited in present claim 1.

For the reasons set forth above, it is submitted that the pharmaceutical compositions described by Yates contain neither cannabis extracts nor cannabis oil in accordance with the presently claimed invention. These prior art compositions of Yates simply contain THC as a single, purified substance. Furthermore, since the

administration forms according to present claim 1 are clearly different from those of Yates in that they comprise a cannabis extract, the subject matter of present claim 1 is novel and patentable over the prior art. Therefore, Yates clearly fails to teach or otherwise disclose every limitation of the present invention as set forth in the present claims and therefore fails to anticipate the present invention. Withdrawal of this rejection is respectfully requested.

Rejection of Claims 1-8, 17-19 and 21 Under 35 U.S.C. 103(a)

Claims 1-8, 17-19 and 21 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Yates. The Examiner argues in the Office action that Yates discloses the limitations of the presently claimed invention, as discussed in detail on pages 9-10 of the present Office action. In particular, the Examiner states that Yates teaches that the concentration of the medication mixed into the reservoir should range from about 0.005% to about 25% (by weight of the total dispersion) and preferably ranging from 0.1% to about 10% and that Yates teaches a thickness for the semi-porous and backing layers of the overall gum pad composition which, when considered individually, fall within the Applicant's recited thickness for "the layer."

The Examiner concedes that Yates fails to take into account the thickness of the medicated reservoir, for which Yates only provides volumetric ranges. The Examiner also states that Yates fails to teach the specific percent weight range for the active medication mixed into the polymeric reservoir matrix. However, the Examiner concludes that since parameters such as the amount of active cannabis agent of the composition and the thickness of the reservoir layer are adjustable, it follows that each is a result-effective parameter that a person having ordinary skill in the art would routinely optimize. Thus,

the Examiner concludes that absent any demonstration of unexpected results from the claimed parameters, optimization of any of these parameters would have been obvious at the time of Applicant's invention.

The Applicant respectfully submits that to establish a *prima facie* case of obviousness, three basic criteria must be met, as set forth in M.P.E.P. § 2142. First, there must be some suggestion or motivation to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The Applicant respectfully disagrees with the Examiner's conclusion set forth in the Office action. It would simply not have been obvious for one of ordinary skill in the art to incorporate a cannabis extract (rather than the pure substance THC) into a film-shaped, mucoadhesive administration form. A person skilled in the art would have disregarded the gum pads taught by Yates since, due to their thickness and three-layered constitution, would be expected to cause an unpleasant or even painful feeling in a patient's mouth. As can be seen, for example from Figure 3 of Yates, these gum pads are rather bulky when mounted on the gums and this will become even worse when the volume of the pads increases due to swelling.

Furthermore, since the membrane (and presumably the backing layer) are not soluble in saliva (Yates, col. 6, lines 54-55; col. 12, lines 43-47), the gum pads will not dissolve completely. Therefore, upon dissolution of the reservoir, the patient would be required to remove the undissolved remains from his or her mouth. In the case of bedridden patients, there would be a considerable risk of choking. Due to these clear

disadvantages, one skilled in the art would not have even considered to refer to the teachings of Yates.

Still further, the film-shaped administration forms of the present invention could not have been easily obtained merely by reducing the thickness of the three layers which form the essential components of the gum pads described by Yates. Since the combined thickness of the backing layer and membrane of the prior art gum pads (even without considering the presence of the reservoir layer) already exceeds the thickness of the film-shaped administration form of the present invention, it is submitted that one skilled in the art would not have considered the possibility of optimizing the gum pads of Yates in order to obtain a film-shaped administration form having a total thickness of 0.5 mm or less.

Clearly, the teachings of Yates fail to make the presently claimed invention obvious. It is therefore respectfully submitted that the present invention defined in the presently amended claims is patentably distinguishable over the prior art teachings under 35 U.S.C. 103(a). Based on the aforementioned differences, each and every element of the present invention recited in the present claims is not set forth in Yates, nor would one skilled in the art be motivated to modify Yates to arrive at the presently claimed invention. Therefore, the Applicant respectfully requests that this rejection be withdrawn.

Conclusion

For the foregoing reasons, it is believed that the present application, as amended, is in condition for allowance, and such action is earnestly solicited. Based on the foregoing arguments, amendments to the claims and deficiencies of the prior art

references, the Applicant strongly urges that the obviousness-type rejection and anticipation rejection be withdrawn. The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

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